Veterinary Medicine Research and Development
Pfizer Inc
7000 Portage Road 0225-190-43
Kalamazoo, MI 49001-0199
Tel 269 833 2482 Fax 269 833 2707

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Pfizer Animal Health

15 July 2005

John W. Hallberg, D.V.M., Ph.D.
Associate Director
Regulatory Affairs

Food and Drug Administration
Division of Dockets Management
HFA-305
5600 Fishers Lane
Rockville, MD 20857

Dear Sirs:

RE: Suitability Petition for Review and Action for a Generic Version of a Ceftiofur Hydrochloride Sterile Suspension

Pharmacia & Upjohn Company (P&U), a Division of Pfizer Inc, submitted a suitability petition for FDA review on 24 June 2005. This letter requested FDA's permission to submit an abbreviated new animal drug application (ANADA) for a generic version of EXCENEL® RTU, ceftiofur hydrochloride sterile suspension as approved under NADA 140-890. A copy of the letter is attached. P&U requests withdrawal of this petition without prejudice.

Please contact me at (269) 833-2482 if you have any questions on this submission.

Sincerely,

John W. Hallberg, D.V.M., Ph.D.

JWH/cs
Enclosure

2005P-0277

WDL1

Veterinary Medicine Research and Development
Pfizer Inc
7000 Portage Road 0225-1
Kalamazoo, MI 49001-0199
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Pfizer Animal Health

John W. Hallberg, D.V.M., Ph.D.
Associate Director
Regulatory Affairs

24 June 2005

Dr. John K. Harshman, Acting Staff Chief (HFV-104)
FDA/Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Dear Dr. Harshman:

RE: Suitability Petition for Review and Action for a Generic Version of a Ceftiofur Hydrochloride Sterile Suspension

Pharmacia & Upjohn Company (P&U), a Division of Pfizer Inc. is submitting this suitability petition for FDA review and concurrence. P&U is requesting FDA's permission to submit an abbreviated new animal drug application (ANADA) for a generic version of EXCENEL® RTU, ceftiofur hydrochloride sterile suspension as approved under NADA 140-890. P&U is proposing one modification to the existing product label for EXCENEL RTU. P&U proposes to limit the route of injection to only the subcutaneous route of administration for cattle instead of both subcutaneous and intramuscular routes as approved for the pioneer product. The suitability petition is attached to this letter. P&U requests FDA's prompt approval of this petition.

Please contact me at (269) 833-2482 if you have any questions on this submission.

Sincerely,

John W. Hallberg, D.V.M., Ph.D

JWH/cs
Attachments